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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference KSW/RTB/38774	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB 03/04174	International filing date (day/month/year) 25.09.2003	Priority date (day/month/year) 25.09.2002
International Patent Classification (IPC) or both national classification and IPC A61M5/32		
Applicant NMT GROUP PLC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 23.04.2004	Date of completion of this report 02.12.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Ehram, F Telephone No. +49 89 2399-2343 

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International application No. PCT/GB 03/04174

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, Pages

1-9 as originally filed

Claims, Numbers

1-21 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
 - ☐ the claims, Nos.:
 - ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-21
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations

see separate sheet

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EXAMINATION REPORT - SEPARATE SHEET**

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The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

- D1: WO 03/051436 A (MAGGIONI TARCISIO ;TECNEDIL SRL (IT)) 26 June 2003 (2003-06-26)
- D2: WO 02/068025 A (MAXXON INC) 6 September 2002 (2002-09-06)
- D3: US-A-5 221 262 (KITE JOHN P) 22 June 1993 (1993-06-22)
- D4: US-A-5 385 551 (SHAW THOMAS J) 31 January 1995 (1995-01-31)
- D5: FR-A-1 006 260 (DORMOY JULES-MARIE-JOSEPH) 21 April 1952 (1952-04-21)
- D6: US-A-6 015 438 (SHAW THOMAS J) 18 January 2000 (2000-01-18)
- D7: WO 02/087669 A (NMT GROUP PLC ;TARGELL JOHN (GB)) 7 November 2002 (2002-11-07)

See point V of the report:

1. The present application does not meet the requirements of Article 33 (2) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33 (2) PCT. Indeed, document D2 discloses all the features of claim 1, in particular figure 4 shows a plastic portion which is not in contact with the prefilled contents of the syringe, see in particular figure 4, the element referenced as 44 and covered by the seal (42) of the piston (20). The same objection applies for document D5 and the intermediate documents D1 and D7 in particular the figures which are showing a plastic portion which is not in contact with the prefilled contents of the syringe.
2. Furthermore, the subject-matter of claims 1-21 lacks inventive step (Art. 33 (3) PCT.
A pre-filled hypodermic syringe is already known from the document D3, where a plastic portion is not in contact with the prefilled contents of the syringe, see figure 4 and abstract.
The sole difference of the subject-matter of claim 1 over D3 is that the piston of D3 is not provided by a piston member.
However, if the skilled man would wish to improve the ejection of the needle, he would have used the known system as disclosed in D4, col. 10, line 47-66 and figures 4 and 5. One skilled in the art would have thus arrived at the syringe of the present invention.

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The subject-matter of the above mentioned claims does therefore not appear to involve an inventive step.

3. The description should have been brought into conformity with the new claims to be filed; care should be taken during revision, especially of the introductory portion including any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Art. 34 2) b)).
4. To meet the requirements of Rules 6 3 b) the independent claim should have been properly cast in a two part form, with those features which in combination are part of the nearest prior art being placed in the first part.
5. To meet the requirements of Rule 5.1 a vi, the cited documents should have been identified in the description and the relevant background art therein is to be indicated.
6. The features of the claim/s should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
7. It is also mentioned that although claims 1 and 2 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1 and 2 do not meet the requirements of Rule 6 PCT.